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EXAMINER	
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1647	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,722	WALLACH ET AL.	
	Examiner	Art Unit	
	Cherie M. Woodward	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *104-119* is/are pending in the application.

4a) Of the above claim(s) *108-119* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *104* is/are rejected.

7)☒ Claim(s) *105-107* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Formal Matters

1. Applicant's amendments to the claims and the specification filed 27 August 2007, are acknowledged and entered. Claims 1-103 have been cancelled by Applicant. Claims 104-119 are pending. Claims 108-119 were previously withdrawn from consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention. Applicant elected Group II, drawn to a polypeptide fragment and elected species of SEQ ID NO: 22. Claims 104-107 and the species of SEQ ID NO: 22 are under examination.

2. It is noted that the Office Action Summary sheet mailed 2/20/2007 listed claims 104-111 as the claims under examination. This notation was a typographical error, as rejections were made over claims 104-107 only (refer to the text of the Office Action mailed 2/20/2007). Claims 108-111 are drawn to non-elected inventions comprising different species of polypeptide, which differ from SEQ ID NO: 22 or its fragments. Once the claims are in condition for allowance, Applicant would be eligible for a further species election. It is noted that Applicant acknowledged and responded to each of the examiners grounds of rejection and in doing so, indicates an understanding that the rejections were only drawn to claims 104-107. Accordingly, the examiner determines that Applicant has been afforded notice and that Applicant's response of 27 August 2007, is indicative that Applicant has understood that notice and has had an opportunity to adequately respond.

Response to Arguments

Election/Restrictions

3. The finality of the restriction requirement was set forth in the previous Office Action at page 2, first paragraph. Applicant traverses the finality of the restriction requirement and requests reconsideration thereof. Pursuant to MPEP 818.03(c), Applicant may petition the Director for review of the restriction requirement (see also 37 CFR 1.181 and 37 CFR 1.144). Applicant is also reminded of the two month requirement for filing of a petition (see 37 CFR 1.181(f)).

Applicant argues that all of the newly added claims (104-119) share a common technical feature. Applicant's arguments have been fully considered, but they are not persuasive.

Multiple distinct products and processes were presented in claims 22-27, 42-54, and 75-95, by preliminary amendment, filed 22 June 2005. The claims filed in the preliminary amendment lacked unity of invention as being anticipated by Sugamura et al., US Patent 5,510,259 (23 April 1996), as stated in the

Requirement for Restriction Election mailed 7 August 2006. In response to the Restriction requirement, Applicant cancelled all of the originally presented claims and added new claims 104-119. New claims 104-111 corresponded to Group II of the preliminary amendment, claims 112-114 corresponded to Group III of the preliminary amendment, claim 115 corresponded to Group IV of the preliminary amendment, and claims 116-119 corresponded to Group V of the preliminary amendment.

The new claims added on 6 November 2007 are drawn to a polypeptide (claims 104-111), a DNA, vector, and host cell (claims 112-114), a method for producing a polypeptide (claim 115), antibodies or antibody fragments drawn to different epitopes (each of claims 116-119). Because the newly added claims corresponded directly with the claims presented in the preliminary amendment which lacked a special technical feature, and thus, lacked unity, the Restriction requirement was deemed proper and was made FINAL. A First Action on the Merits reflecting the same was mailed on 20 February 2007.

With respect to a group of inventions claimed in an international application, unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" is defined in PCT Rule 13.2 as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art. The determination is made on the contents of the claims as interpreted in light of the description and drawings (if any). Whether or not any particular technical feature makes a "contribution" over the prior art, and therefore constitutes a "special technical feature," is considered with respect to novelty and inventive step. For example, a document discovered in the international search shows that there is a presumption of lack of novelty or inventive step in a main claim, so that there may be no technical relationship left over the prior art among the claimed inventions involving one or more of the same or corresponding special technical features, leaving two or more dependent claims without a single general inventive concept. Lack of unity of invention may be directly evident "a priori," that is, before considering the claims in relation to any prior art, or may only become apparent "a posteriori," that is, after taking the prior art into consideration. In the instant case, the Sugamura et al., reference anticipated Group I (claims 22-27 and 42 of the preliminary amendment). Applicant cancelled all of the claims in the preliminary amendment, but added new claims which corresponded to the Groups as set forth in the Requirement for Restriction/Election. On page 2 of Applicant's response (listed as page 21 of 24), filed 6 November 2006, Applicant elects the polypeptide of 41MDD comprising residues 329-369 of SEQ ID NO: 22 (see third full paragraph). Although only claims 104 and 105 are drawn to the elected polypeptide comprising residues 329-369 of SEQ ID NO: 22,

claims 106 and 107 read on polypeptide fragments of SEQ ID NO: 22 that also comprise the elected residues. As such, claims 106 and 107 were examined together with claims 104 and 105.

Applicant is encouraged to review MPEP 1850, which states, in pertinent part: pursuant to 37 CFR 1.475, a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention "). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features " shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. A national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or

(2) A product and a process of use of said product; or

(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

(c) If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.

(d) If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and § 1.476(c).

(e) The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

Speaking hypothetically and for exemplary purposes only, in an effort to assist Applicant in understanding the Examiner's position, even if the Sugamura et al. patent ('259 patent) had not caused a lack of unity in the claims presented in the preliminary amendment, MPEP 1850 and 37 CFR 1.475 would still have restricted the inventions to the first product, the first method of making, and the first method of using. The amended the claims would have still required restriction as set forth above (see MPEP 1850 and 37 CFR 1.475). Claims 104-111, would have required election as the first claimed product, and claim 115 would have been joined as the method of making. No claims reflect a method of using the polypeptide. Thus, even if the Sugamura et al., patent ('259 patent) had not caused a lack of unity (as anticipatory art), claims 104-111 and 115 would have been the only claims under examination. Further, because of the species election of SEQ ID NO: 22, claims 108-111 would have also been withdrawn as being drawn to non-elected inventions, there being no allowable generic or linking claim.

If Applicant wishes to petition the Director for the addition of claim 115 (method of making the polypeptide), the mechanism for doing so is set forth in the citations above. However, Applicant is also reminded that because a First Action on the Merits was mailed in this case on 20 February 2007, this invention has been constructively elected by original presentation for prosecution on the merits. See 37 CFR 1.142(b) and MPEP § 821.03. The Examiner hopes that this summary has clarified any concerns of Applicant or Applicant's representative. Applicant's representative is encouraged to contact the examiner if he has any additional questions.

Specification

4. The objection to the use of the trademark CLONTECH (p. 47) is maintained. Applicant argues that the trademark "CLONTECH" is a trade name and not a trademark. Applicant's argument has been fully considered, but it is not persuasive. A printed image of the TESS USPTO trademark database is provided showing the standard character mark SN:77096260, "CLONTECH" (see NPL attachment). Applicant is referred to the applicable classes and uses of the mark as set forth in the TESS registration.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

5. Applicant's correction of numerous typographical errors in the specification is noted and is greatly appreciated.

Claim Rejections Withdrawn

6. The rejection of claims 104-107 remain rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter, is withdrawn in light of Applicant's amendments to the claims.

7. The rejection of claims 104-107 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, as containing new matter, is withdrawn in light of Applicant's amendments.

8. The rejection of claims 104-107 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, regarding the functional requirement as being "capable of binding to NIK," is withdrawn in light of Applicant's amendments.

9. The rejection of claim 104 under 35 U.S.C. 102(b) as being anticipated by Rothe et al., US Patent 5,844,073 (1 December 1998) is withdrawn in light of Applicant's amendments to the claim.

10. The rejection of claims 104-107 under 35 U.S.C. 112, first paragraph, scope of enablement, is withdrawn in light of Applicant's amendments.

11. The rejection of claims 105-107 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement are withdrawn.

Claim Rejections Maintained

Claim Rejections - 35 USC § 112, First Paragraph

Written Description

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 104 remains rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the

specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

It is noted that the Office Action mailed 20 February 2007 contained a typographical error identifying claims 22-31. However, the record is clear that claims 22-31 have been cancelled prior to a first action on the merits. The examiner apologizes for this typographical error. However, Applicant's response, filed 27 August 2007, indicates that the Applicant has understood the rejection and has been afforded an opportunity to respond accordingly, as noted by Applicant's lengthy response to the written description rejection (see pages 46-53 of the 27 August 2007 Response). Accordingly, the examiner determines that Applicant has been afforded notice and that Applicant's response of 27 August 2007, is indicative that Applicant has understood that notice and has had an opportunity to adequately respond.

Applicant's arguments (pp. 47-52 of the Response filed 27 August 2007) are drawn to the limitation in claim 104 subpart (c) which recites a 95% identity limitation. Applicant argues that this 95% variation results in no more than 4 possible amino acid substitutions, deletions, or additions, which still retain NIK binding function. Applicant bases this argument on the fact that the intracellular domain of cγc comprises 86 amino acids (residues 284-369 of SEQ ID NO: 22). With respect to variants of fragments (subpart (c) that is read in the alternative to subpart (b)), Applicant argues that the number of amino acids which can be varied will be reduced depending on the size of the fragment. Applicant argues that this results in no more than a modest genus. In support of their arguments, Applicants cite Ex Parte Kubin (2007-0819, BPAI 31 May 2007, 2007 Pat. App. LEXIZ 13, May 31, 2007) and Example 14 of the Written Description Guidelines (USPTO Guidelines for the Examination of Patent Applications Under 35 USC 112, paragraph 1, "Written Description" Requirement and the accompanying synopsis) (see Response filed 27 August 2007, pp. 49-52). Applicant's arguments have been fully considered, but are not fully persuasive.

"The 'written description' requirement [under 35 U.S.C. § 112, first paragraph,] implements the principle that a patent must describe the technology that is sought to be patented; the requirement serves both to satisfy the inventor's obligation to disclose the technologic knowledge upon which the patent is based, and to demonstrate that the patentee was in possession of the invention that is claimed." Capon v. Eshhar, 418 F.3d 1349, 1357, 76 USPQ2d 1078, 1084 (Fed. Cir. 2005).

The examiner agrees that Applicant has sufficiently described a polypeptide that binds to NIK consisting of the intracellular domain of cγc (residues 284-369 of SEQ ID NO: 22) (claim 104, subpart (a)). Additionally the examiner agrees that Applicant has sufficiently described a polypeptide that has

95% sequence identity and binds to NIK consisting of the intracellular domain of cγc (residues 284-369 of SEQ ID NO: 22) (claim 104, subpart (c) in the first alternative – as part (a)).

However, Applicant's alternative claim language necessitates maintaining the instant rejection as it pertains to a variant of a fragment (claims 104, subpart (c) in the alternative to subpart (b). Applicant has not sufficiently described a polypeptide variant of a fragment of the intracellular domain of cγc (residues 284-369 of SEQ ID NO: 22) (claim 104, subpart (c) in the second alternative – as part (b)) that has at least 95% sequence identity to the fragment and binds to NIK.

It is noted that the limitations as to a functional derivative (claim 104, subpart (d)) are imported from the definition of a "functional derivative" in the specification (p. 23). There are no examples provided in the specification which exemplify the defined functional derivatives. Although examples are not required, they are helpful in determining whether Applicant was in possession of the invention, in this case the claimed genus of functional derivatives as defined by the specification and claim 104, subpart (d). It is also noted that fragments and variants which fail to meet the limitations of binding to NIK all together, fall outside the scope of the claims. While "examples explicitly covering the full scope of the claim language" typically will not be required, a sufficient number of representative species must be included to "demonstrate that the patentee possessed the full scope of the [claimed] invention." Lizardtech v. Earth Resource Mapping, Inc., 424 F.3d 1336, 1345, 76 USPQ2d 1724, 1732 (Fed. Cir. 2005).

With respect to Applicant's reliance on hypothetical Example 14 of the Written Description Guidelines, "[c]ompliance with the written description requirement is essentially a fact-based inquiry that will 'necessarily vary depending on the nature of the invention claimed" *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). While the Written Description Guidelines and hypothetical examples in the Synopsis can be helpful in understanding how to apply the relevant law, as it existed in 2001 when the Guidelines were adopted, but they do not create a rigid test. Example 14 of the Written Description Guidelines is drawn to a product by function in which the hypothetical claims are drawn to a genus of variants with 95 % homology to a novel and unobvious protein. Example 14 is only analogous to instant claim 104, subpart (c) in the first alternative, as directed to subpart (a). It is not applicable to subpart (b) because subpart (b) recites a variant of up to 95% of a fragment of an unspecified length. In other words, although the amino acid sequence of subpart (a) is known, identifiable, and limited because of the "consisting of" language in the claim, and 95% of the full-length sequence amounts to no more than 4 amino acid variations (encompassing subpart (c) in the alternative directed to subpart (a)), the structure of "fragments" in subpart (b) may be of any length, so long as they

consist of the amion acids recited in subpart (a). Applicant's own definition of "fragments" (as discussed above) makes it difficult to determine the structure and composition of the variants of fragment in subpart (c), when read in the alternative as directed to subpart (b).

Applicant draws the Examiner's attention to Table 1 (pp. 47-48), Table 2 (p. 49), and Table 3 (p. 51) for the purpose of demonstrating that Applicant was in possession of fragments and variants. Table 1 (p. 48) shows that residues 289-357 (with 12 AA deleted from the membrane distal domain) and 289-325 (with 44 AA deleted from the intracellular domain) both bound to NIK. [Examiner note – all referenced amino acid residues are from and in relation to SEQ ID NO: 22.] Table 2 (p. 49) shows that residues 329-369 (the 41MDD polypeptide) bound to both NIK (presumably the full length protein) and to NIK624-947 (C-terminus of NIK), although it poorly bound to the full length NIK. The specification also states that the region of 44 amino acid residues spanning "282-235" (44MPD) can also bind NIK (p. 49, lines 14-15). It appears that there is a typographical error in the recited spanned region. 44 amino acid residues starting at residue 282 would mean that the last residue was 325. As such, the examiner will read this region as 282-325 (44MPD). Table 3 (p. 51) shows that all of the following substitution fragments bound to NIK, albeit with varying degrees of binding strength: fragment 289-369 with P336A, P337A, P360A, P361A, K338A, E344A, W358A. Applicant's exemplified fragments and single amino acid substitution variants shown in Tables 1, 2, and 3 meet the limitations of the claims as set forth in subparts (a), (b), and (c) as drawn to first alternative to subpart (a), and are described.

The specification defines "fragments" on page 23 as "any fragment or precursor of the polypeptide chain compound itself, alone or in combination with related molecules or residues bound to it, for example residues of sugars or phosphates, or aggregates of the polypeptide molecule when such fragments or precursors show the same activity of the polypeptides of the invention…" (p. 23, lines 21-25). The term "variants" is not otherwise defined in the specification, but Applicant does define muteins or mutants of the protein, which can be considered "variants." "Such 'muteins' may be ones in which up to about 25% and preferably under 12% amino acid residues may be deleted, added, or substituted by others in the polypeptide, such that modifications of this kind do not substantially change the biological activity of the protein mutein with respect to the protein itself…" (p. 24, lines 23-26). Using Applicant's definition of a mutein for that of a variant (as recited in claim 104, subparts (c) and (d), the 86 amino acid intracellular domain would potentially comprise "about" 22 (25% of 86 residues = 21.5) distinct substitutions mutations or deletions anywhere throughout the length of the 86 amino acid sequence.

Table 1 (pp. 47-48) demonstrates that deletion variants, for example, do not have to be in the membrane proximal region, but may occur at any place over the 86 amino acid sequence. For example,

the full-length intracellular region spans from residue 284 to residue 369 of SEQ ID NO: 22. One of the exemplified deletion mutants in Table 1 spans from residue 289 to residue 357. Another one of the exemplified deletion mutants in Table 1 spans from residue 289 to residue 325. Although, admittedly, the latter 289-325 deletion mutant would qualify as a "fragment" under Applicant's definition and not a "mutein" or variant because the example, itself reads on a 44 amino acid deletion, which is far greater than Applicant's definition of a "mutein," comprising about 25% variance (i.e. 22 residues) in the deletion, addition, or substitution. Applicant's own definition in the specification which encompass limits of the structure (i.e. about 25% variants for muteins [read as variants], and greater variance for fragments, as demonstrated by the 289-235 "fragment" of Table 1) adds to the difficulty and confusion of determining whether Applicant was in possession of a sufficient number of species of "variants of fragments."

Because the examples set forth in the specification show the potential for a large number of variants of fragments (as set forth in subpart (b) in the alternative to subpart (c)), encompassing any length or from any portion of the intracellular region of residues 284-369 of SEQ ID NO: 22, Applicant's arguments that the claims are limited to no more than 4 additions, substitutions, or deletions, is not well taken. The single variant fragment disclosed in Table 1, which spans from residue 289 to residue 325 of SEQ ID NO: 22, illustrates the difficulty of determining whether Applicant was in possession of a sufficient number of the members of the genus of variants of fragments because the example reads on a 44 amino acid deletion, which is far greater than the structural limitations set forth in Applicant's definition of a "mutein," [read as a variant] which states "about 25% variance" (i.e. 22 residues) meets the definition of a mutein. The 44 amino acid deletion for the exemplified variant fragment is greater than either Applicant's definition of "mutein" [read as variant] in the specification and the 95% variants argued by Applicant. As such. Applicant's arguments are therefore applied only to claim 104, subpart (a) (b) and subpart (c) in the first alternative (as it relates to subpart (a)), and (d) (as it applies to the aforementioned subparts). Applicant has not set forth a sufficient description of the claimed "variants of fragments" to establish that Applicant was in possession of a sufficient number of representative species at the time of filing. Although the alternative claimed embodiments of variants of fragments encompass a function (i.e. binding to NIK), the structural limitations are not adequately described.

With respect to Applicant's reliance on Ex Parte Kubin. Applicant appears to selectively drawn from the part of the opinion that focuses on percent homology, arguing that the instant amendment to 95% homology in claim 104, subpart (c) is sufficient for the instant claims to meet the structural requirements set forth in Ex Parte Kubin. Applicant's argument in this regard is understood by the examiner, but is not

relevant to claim 104, subpart (c) as it is recited in the alternative as dependent on subpart (b), which reass on variants of fragments. Additionally, it is suggested that Applicant revisit Ex Parte Kubin decision and take the decision, particularly as it relates to a written description rejection, as a whole. Possession may not be shown by merely describing how to obtain possession of members of the claimed genus or how to identify their common structural features (see, Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 927, 69 USPQ2d 1886, 1895 (Fed. Cir. 2004); accord Ex Parte Kubin, 2007-0819, BPAI 31 May 2007, opinion at p. 16, paragraph 1). In light of the foregoing, one of skill in the art would not recognize from the disclosure that the applicant was in possession of the claimed genus pf variants of fragments (subpart (c) in the second alternative to subpart (b).

New Claim Objections/Rejections – Necessitated by Amendment

Claim Objections

14. Claim 105-107 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claims, or amend the claims to place the claims in proper dependent form, or rewrite the claims in independent form.

Claims 105, 106, and 107 are each dependent on claim 104, which is read in various alternatives. Claim 104 (the independent claim) recites the closed language "consisting of." However, dependent claims 105, 106, and 107 recite open language "comprising." The use of closed language in the independent and open language in the dependent claims renders the dependent claims broader than the independent claim. As such, it does not appear that the dependent claims 105, 106, and 107, further limit independent claim 104. See, Genentech, Inc. v. Chiron Corp., 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997), holding that "'[c]omprising' is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim." Additionally, the transitional phrase "consisting of" excludes any element, step, or ingredient not specified in the claim. See, In re Gray, 53 F.2d 520, 11 USPQ 255 (CCPA 1931); and Ex parte Davis, 80 USPQ 448, 450 (Bd. App. 1948) holding that "'consisting of' is defined as 'closing the claim to the inclusion of materials other than those recited except for impurities ordinarily associated therewith." See also, MPEP 2111.03.

Allowable Subject Matter

15. Claims 105-107 are objected to under 37 CFR 1.75(c) and as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claim, which includes the recitation of the "consisting of" language from the base claim.

Conclusion

Claim 104 remains rejected.

Claims 105-107 are objected to.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cherie M. Woodward whose telephone number is (571) 272-3329. The examiner can normally be reached on Monday - Friday 9:00am-5:30pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CMW/
AU 1647

/Manjunath N. Rao, /
Supervisory Patent Examiner, Art Unit 1647